DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3641N

Food and Drug Administration
Rockville MD 20857

Warning Letter

APR 12 2000

Mr. Haye Hinrichs
Vice President/C.O.O.
Satelec - Amadent
1236 Brace Road, Building B
Cherry Hill, New Jersey 08034

Dear Mr. Hinrichs:

On October 28, 1999, we wrote to you advising that Satelec - Amadent's commercial distribution of a glass bead dry heat sterilizer is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) due to the fact that clearance has not been granted by the U.S. Food and Drug Administration. At that time, we also provided a copy of an advertisement found on Amadent's website clearly indicating that Satelec - Amadent is promoting the sale of such a device. We asked that you respond to our letter within twenty (20) days concerning this apparent violation of the Act. We have yet to receive a response from you.

A glass bead dry heat sterilizer is considered to be a medical device under 201(h) of the Act. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country. While your device has been on the market for sometime, as of January 1997 the agency called for either a Premarket Approval Application or Product Development Protocol for these devices. Our records do not show that you have submitted either.

Because you do not have marketing clearance from FDA, marketing your device is a violation of the law. In legal terms, the sterilizer is adulterated under section 501(f)(1)(B) of the Act because you have not obtained premarket approval since January 1997 based on information developed by you that shows your device is safe and effective.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this

from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Sharon Kalokerinos, Dental, ENT, and Ophthalmic Devices Branch, 2094 Gaither Road, Rockville, Maryland 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1 (800) 638-2041 or through the Internet at www.fda.gov and clicking on Center for Devices and Radiological Health.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter please feel free to call Sharon Kalokerinos at (301) 594-4613.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health